

REMARKS

Claims 1-5, 14, 15, 23, 28, 38, 49, 53, 55, 56, and 62 were previously pending in this application. Claims 1, 14, 15, 53, 55, 56, and 62 have been amended. New claims 77-79 have been added. As a result claims 1-5, 14, 15, 23, 28, 38, 49, 53, 55, 56, 62, and 77-79 are pending for examination with claims 1, 14, 15, 23, 28, 38, 49, 53, 55, 56, 62, and 77 being independent claims. No new matter has been added.

Allowable Subject Matter

Applicants thank the Examiner for finding that claims 23, 28, 38, and 49 are allowed.

Rejections Under 35 U.S.C. §102

A. Independent claims 1, 14, 15, 53, 55, 56, and 62 together with several of their respective dependent claims, stand rejected under 35 U.S.C. §102(b) as being anticipated by Kuriyama (U.S. 5,728,577).

1. Claims 1 and 53

Claims 1 and 53 have been amended to further clarify that the matrix assembly includes at least one rigid three-dimensional porous solid matrix member carried by the support, where the porous solid matrix member is a unitary structure. Support for this amendment can be found on page 8, lines 9-11, and page 21, line 33. Kuriyama teaches a treatment tank with at least one carrier member having a carrier body 23 formed of a porous material. Although the carrier body is formed of a porous material, it is positioned between a rigid inner sleeve 24 and a rigid outer sleeve 25, which each act as a reinforcement member to the porous material. In column 4, lines 52-66 of Kuriyama, the porous material is described as being a soft material, such as an open-cell rubber foam, a non-woven fabric, or a polypropylene fiber. The porous material is further described as not inherently having self-sustainability. Thus, it is respectfully submitted that Kuriyama fails to teach at least one *rigid three-dimensional porous solid matrix member*.

Therefore, it is respectfully requested that the Examiner withdraw the rejection of claims 1 and 53 in view of Kuriyama, as the prior art fails to teach at least these recitations of claims 1 and 53. Claims 2-5, depending on claim 1, are allowable for at least the same reasons.

2. Claims 14, 15, 55, and 56

Claims 14, 15, 55, and 56 have similarly been amended to further clarify that the apparatus for culturing cells includes at least one *rigid* three-dimensional porous matrix member. As described above Kuriyama does not teach or suggest a rigid three-dimensional porous solid matrix member as now recited in amended claims 14, 15, 55, and 56. Therefore, claims 14, 15, 55, and 56 are believed to be in allowable condition for at least this reason, and the rejection should be withdrawn.

3. Claim 62

Method claim 62 has been amended to clarify that the method for in vitro culture of cells includes introducing an amount of cells into a *rigid* three-dimensional porous solid matrix having interconnected pores of a pore size sufficient to permit the cells to grow throughout the matrix, where the porous solid matrix is a unitary structure. As discussed above, Kuriyama does not teach or suggest the use of a rigid three-dimensional porous solid matrix as now recited in amended claim 62. Thus, claim 62 patentably distinguishes over Kuriyama, such that the rejection should be withdrawn.

B. Independent claims 1, 53, and 62 and the claims depending therefrom are rejected under 35 U.S.C. §102(b) as being anticipated by Hitachi (JP 04-126068).

1. Claims 1 and 53

As discussed above, claims 1 and 53 have been amended to further clarify that the matrix assembly includes at least one rigid three-dimensional porous solid matrix member carried by the support, where the porous solid matrix member is a unitary structure. Based upon the English abstract and figures, Hitachi teaches an apparatus having a support shaft onto which a plurality of perforated plates are mounted. The support shaft is fixed to a vessel and cells within the vessel adhere to the perforated plates.

Hitachi fails to disclose a matrix assembly including *at least one rigid three-dimensional porous solid matrix member, where the porous solid matrix member is a unitary structure*, as

now recited in amended claims 1 and 53. Figure 3 of Hitachi, appears to disclose one embodiment where the plates include a packed bead arrangement. While a bead arrangement may serve as a support for cell cultures, the bead arrangement is not a *unitary structure* as now recited in amended claims 1 and 53. As indicated in the specification of the present invention on page 8, lines 9-11, solid unitary structures are specifically meant to not include beads or packed beads arrangements. A solid unitary structure is advantageous over a bead arrangement because there is no internal movement associated with a unitary structure. In a bead arrangement, the beads may move around, and thus collide with each other. Such collisions may damage the cells located on the outer surface of the beads. This damage may reduce the total number of cells produced in the culturing device. Thus, Hitachi does not teach or suggest *at least one rigid three-dimensional porous solid matrix member, where the porous solid matrix member is a unitary structure*. Therefore, claims 1 and 53, and any claims depending therefrom, are believed to be in allowable condition for at least this reason, and the rejection should be withdrawn.

2. Claim 62

As discussed above, method claim 62 has been amended to clarify that the method for in vitro culture of cells includes introducing an amount of cells into a rigid three-dimensional porous solid matrix having interconnected pores of a pore size sufficient to permit the cells to grow throughout the matrix, where the porous solid matrix is a unitary structure. As discussed above, Hitachi does not teach or suggest a *rigid three-dimensional porous solid matrix, where the porous solid matrix is a unitary structure* as now recited in amended claim 62. Thus, the rejection should be withdrawn for at least this reason.

C. Independent claims 1, 53, and 62 together with several of their respective dependent claims, stand rejected under 35 U.S.C. §102(b) as being anticipated by Krovak et al. (U.S. 4,683,062).

1. Claims 1 and 53

As discussed above, claims 1 and 53 have been amended to clarify that the matrix assembly includes at least one rigid three-dimensional porous solid matrix member carried by the

support, where the porous solid matrix member is a unitary structure. Krovak teaches a method of circulating a liquid phase through a solid phase in a rotatable body. Krovak describes the solid phase 14 in column 4, lines 46-50, as usually including particles of immobilized enzymes or cells, that are loose, permeable, and amorphous.

Krovak, however, does not teach or suggest a rigid three-dimensional porous solid matrix member where the *porous solid matrix member is a unitary structure*, as now recited in amended claims 1 and 53. Although the solid phase in Krovak may be porous, a loose amorphous mixture is not a *unitary structure*. Further in column 4, lines 64-68, Krovak discloses that the “solid phase” may alternatively include a paste-like gelatinous or similar consistency material through which a liquid may pass. However, gelatinous material is a semi-solid, not a rigid solid structure, and such a material is not a unitary structure either.

The present invention may be advantageous over arrangements which employ non-unitary structures, such as a gelatin. While using a culturing device, it may be important to be able to obtain an aliquot sample that is representative of the cell count for the entire culturing device. Typically, the cell count for the aliquot sample is dependent on the porosity of the aliquot sample. Therefore, the cell count for the aliquot sample of a porous structure with a varying porosity, such as gelatin, does not accurately reflect the cell count for the entire porous structure. However, the cell count for an aliquot sample of a uniform porosity structure of one embodiment of the present invention will be an accurate reflection of the cell count for the entire porous structure.

Accordingly, Krovak does not teach or suggest a rigid three-dimensional porous solid matrix member where the porous solid matrix member is a unitary structure, as now recited in amended claims 1 and 53. Thus, the rejection should be withdrawn for at least this reason.

2. Claim 62

As previously discussed, method claim 62 has been amended to clarify that the method for in vitro culture of cells includes introducing an amount of cells into a rigid three-dimensional porous solid matrix having interconnected pores of a pore size sufficient to permit the cells to grow throughout the matrix, where the porous solid matrix is a unitary structure. As discussed

above, Krovak does not teach or suggest a *rigid three-dimensional porous solid matrix where the porous solid matrix is a unitary structure* as recited in amended claim 62.

In addition, Krovak fails to teach a method for in vitro culture of cells. Krovak teaches a method of circulation with employs centrifugal forces. The liquid in Krovak moves up through the solid phase due to a pressure gradient from top to bottom. Although as described in Krovak in Column 8, lines 61-64, such a design may be sufficient for the treatment of waste waters in ponds and reservoirs, this design would be damaging to cell growth.

Therefore, it is respectfully requested that the Examiner withdraw the rejection of claim 62 in view of Krovak, as the prior art fails to teach at least these recitations of amended claim 62.

Additional Claims

Applicant has added new claims 77-79 to further define the invention. Claim 77 relates a matrix assembly for culturing cells including a support comprising a shaft and an outwardly extending member extending from and connected to the shaft, and at least one rigid three-dimensional porous solid matrix member carried by the support for movement therewith, where the porous solid matrix member is a unitary structure. The prior art of record fails to disclose this claim combination. Claims 78-79 are dependent on claim 77 and are believed to be allowable for at least the same reasons.

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- 13 -

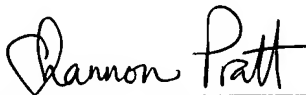
Art Unit: 1744

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

By: 
Neil P. Ferraro, Reg. No. 39,188
Shannon M. Pratt, Reg. No. 55,548
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2211
Telephone: (617) 720-3500

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